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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/980,395	11/28/97	SONTHEIMER	H D5858D1

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HM22/0122

EXAMINER

SUN HOFFMAN, L

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED:

01/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/980,395**

Applicant(s)  
**Sontheimer et al**

Examiner  
**Lin Sun-Hoffman**

Group Art Unit  
**1642**



☒ Responsive to communication(s) filed on Sep 25, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 4 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 and 4 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. Claims 1 and 4 are pending for the examination. Claims 2 and 3 are canceled.

#### **Rejections Maintained:**

Claims 1 and 4 remains rejected under 35 U.S.C. 112, second paragraph. Claims 1 and 4 are vague and indefinite in reciting a chlorotoxin-like protein. The definition of chlorotoxin-like protein lacks metes and bounds. Changing to chlorotoxin protein will obviate the rejection.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBin et al (Am. J. Physiol. 264/2, 33-2 (C361-C369), 1993) in view of Weiss et al (US Patent Number: 5750376, May 12, 1998).

Claim 1 is drawn to a pharmaceutical composition comprising a ligand which binds to glial-derived or meningioma-derived tumor cells and a pharmaceutical acceptable carrier, wherein said ligand is selected from the group consisting of an antibody which recognizes an antigen that is a glioma or meningioma specific chloride channel and a chlorotoxin-like compound. Claim 4 further limits claim 1 in reciting that the ligand of a chlorotoxin-like compound is radiolabeled.

DeBin et al teach a chlorotoxin specifically blocking chloride channels (see abstract). However, DeBin et al differ from the instant invention in failing to disclose a labeled chlorotoxin-

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like ligand. Weiss et al teach a Western blotting assay and a radioimmune assay (see column 34, lines 16-18) which involve in labeling of an antibody, and labeling of an antibody in an immunochemistry assay (see column 36, lines 65-66).

It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to make a composition of chlorotoxin which specifically binds to chloride channels as disclosed by DeBin and to label it. One of ordinary skill in the art would have been motivated to label a chlorotoxin or any of its fusion compound taught by DeBin et al, because it is conventional and it is taught by Weiss et al to label a ligand by a fluorescent agent or a radioisotope to target the tumor cells for the purpose of diagnosis or treatment.

Applicants' argument is moot since the Ullrich et al' reference is not applied.

**New Grounds for Rejections:**

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Uchida et al (J. Clin. Invest., 1, 104-13, Jan. 1995), or under 35 U.S.C. 102(b) as being anticipated by Debin et al (Am. J. Physiol. 264/2, 33-2 (C361-C369), 1993)

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Uchida et al teach an antibody recognizing a 70-KD protein in SDS-PAGE from rat inner medulla and recognizing an in vitro translated CIC-K1 protein (a kidney-specific chloride channel) (see abstract). Since the CLC-5 antibody ( an antibody specific to CLC-5, a kidney expressed chloride channel) is known to recognize a 70-KD GCC (a Glioma Chloride Channel) as evidenced by the specification on pages 56-57, CIC-K1 antibody inherently recognizes the GCC.

DeBin et al teach a chlorotoxin specifically blocking chloride channels (see abstract), therefore, the property of the specificity to the glioma chloride channel is inherently taught as evidenced by the specification.

***Conclusion***

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) -308-4310.

Lin Sun-Hoffman, Ph.D.



January 19, 1999



**PAULA K. HUTZELL**  
**SUPERVISORY PATENT EXAMINER**